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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,091	08/06/2003	Annc M. Pianca	AB-185U	6980

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ADVANCED BIONICS CORPORATION
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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/635,091	Applicant(s) PIANCA ET AL.	
	Examiner Michael Kahelin	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/25/2006 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Examiner could find no support in the specification for the limitation of "wherein the outer covering and inner core are not movable with respect to each other". Additionally, in paragraphs 0043, 0046, and 0047, it is disclosed that the inner core is inserted into the tube. Any negative limitation or

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exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)). Although the specification may or may not disclose an embodiment wherein the two elements are movable, there is no support found for making the two elements immovable with respect to each other.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 5-11, 14, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. (US 6,214,016 hereinafter "Williams").

5. In regards to claim 1, Williams discloses a stylet (42, 44 and 46), comprising an outer metallic covering (element 44 and col. 5, line 37), an inner core (46), and the outer and inner portions have different elastic and buckling properties (col. 5, line 37 and col. 6, line 8). Further, the tube and inner core are not movable with respect to each other (when in the fixed state of column 3, lines 1-23).

6. In regards to claims 2, 14 and 18, the outer covering is a super-elastic metallic material, which is more flexible than the inner core, (col. 5, line 39) and the inner core is

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a linear elastic material (col. 6, line 8), which is more resistant to buckling, and the system comprises a lead (col. 1, line 17). Please note that, since the stylet is inserted into a hollow lead (col. 6, line 63), and there are no permanent fixation means, Williams' stylet can inherently be used more than once.

7. In regards to claim 5, the stylet is isodiametric (Fig. 5).

8. In regards to claim 6, the outer covering has variable wall thickness along the length of the stylet (Fig. 6 – thickness 1 is in the region of 44 and thickness 2 is in the region of 46).

9. In regards to claim 7, the outer covering has a constant wall thickness along the length of the stylet (Figs. 5, 9 and 10).

10. In regards to claim 8, the stylet has variable outer circumference (Fig. 6 - circumference 1 is in the region of 44 and circumference 2 is in the region of 46).

11. In regards to claim 9, the outer covering (44) has constant wall thickness along the length of the stylet (Figs. 6, 9, and 10).

12. In regards to claim 10, the inner core has constant thickness along the length of the stylet (Fig. 11).

13. In regards to claim 11, the inner core material is a super-elastic material (col. 6, line 40), and the outer covering material is a linear elastic material (col. 6, line 3).

14. In regards to claim 17, the outer covering defines a tube having an annulus (Fig. 10).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 13 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Williams. Williams discloses the essential features of the claimed invention, including using a Nitinol inner core that has 8% recoverable strain and a radius of curvature of 0.10 inches (col. 6, line 46) and an inner core that operates on the compression side of the stress-strain curve because the inner tube pushes the lead (Fig. 6), thusly placing the inner tube in a compressive state during pushing. Although Williams does not explicitly disclose that the core is pre-stressed, the core would inherently be required to be pre-stressed to achieve any sort of curvature during deployment. Alternatively, it is well known in the art to pre-stress

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Nitinol elements to impart a shape change for steering or fixation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to pre-stress the inner Nitinol core of Williams' invention to provide a means to steer or fix the structure.

18. Claims 3, 4, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams. Williams discloses the essential features of the claimed invention, including providing an outer covering that defines a tube and annulus (Fig. 10), a non-separable solid stylet, and an outer material of Nitinol (col. 5, line 37), but does not explicitly disclose that the stainless steel of the inner core is 304, 316, or 316L stainless steel. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the stainless steel core as taught by Williams with the 304, 316, or 316L alloys because applicant has not disclosed that these alloys provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the stainless steel as taught by Williams because both materials would provide the desired buckling resistance. Therefore, it would have been an obvious matter of design choice to modify Williams' invention by using 304, 316, or 316L stainless steel to obtain the invention as specified in the claims.

19. Claims 15, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Stoy et al. (US 5,217,026 hereinafter "Stoy"). Williams discloses the essential features of the claimed invention except for providing an outer covering of 304, 316, or 316L stainless steel and an inner core of the claimed

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materials. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the stainless steel outer covering (col. 6, line 3) as taught by Williams with the 304, 316, or 316L alloys because applicant has not disclosed that these alloys provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the stainless steel as taught by Williams because both materials would provide the desired buckling resistance. Therefore, it would have been an obvious matter of design choice to modify Williams' invention by using 304, 316, or 316L stainless steel to obtain the invention as specified in the claims. Furthermore, Stoy teaches of providing a stylet (col. 1, line 27) with a ceramic core (col. 4, line 67) to provide the rigidity required for insertion into the human body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Williams' invention with a ceramic core to provide the rigidity required for insertion into the human body.

Response to Arguments

20. Applicant's arguments filed 9/25/2006 have been fully considered but they are not persuasive. Applicant argued that Williams fails to anticipate independent claims 1, 14, and 18 because Williams' inner and outer core are movable with respect to each other, and the claimed elements are not. However, Williams discloses that the elements are fixed during the implantation procedure (col. 3-line 1-23), thus preventing movement with respect to each other.

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21. Applicant further argued that the combination of Williams and Stoy is impermissible hindsight reconstruction because neither Stoy, nor Williams, disclose an outer metal covering and non-metal inner core; and are non-analogous because Williams discloses a system with movable elements and Stoy discloses a lubricious, hydrogel-coated stylet. However, Williams discloses a composite stylet structure for pushing a lead to a desired location, especially the configuration of Figure 5, which is effectively a composite structure of a stainless steel outer layer (col. 6, line 5) and Nitinol, plastic, polymer, or synthetic inner member (col. 5, line 56) for pushing lead "50". This is a clear indication that other nonmetallic materials are envisioned for the inner member, depending on the desired mechanical characteristics. Stoy discloses a stylet made of metal, plastic, carbon fibers, glass, ceramic, or a combination of materials (col. 4, line 66), which is also a clear indication that Stoy envisions composite stylet structures made of various combinations of the above listed materials. Both references are in the same field of endeavor (stylets for implanting leads) and both teach of the desirability of combining various materials in stylet structures, such as stainless steel and ceramic, to provide desirable mechanical properties. As such, the rejection of claims 15, 19, and 20 under 35 USC 103(a) is still deemed proper and stands.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

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GEORGE R. EVANISKO
PRIMARY EXAMINER

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1/11/07